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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,216	08/05/2003	Stephen Allen Goldman	CM2522C&L	6856

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[REDACTED] EXAMINER

WU, IVES J

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1713

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/634,216	GOLDMAN ET AL.
	Examiner Ives Wu	Art Unit 1713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 July 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 15-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 15-31 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/23/2004</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 through 14 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(1). **Claims 15-31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brandt et al (US004654039) in view of Coles et al (US006613030B1).

(2). Brandt et al disclose a hydrogel-forming polymer (Title) comprising polymerizable, unsaturated, acid-containing monomer including olefinically unsaturated carboxylic acids, olefinically unsaturated sulfonic acids and mixtures thereof (Col. 4, line 65, Col. 5, line 7) and other non-acid monomers (Col. 5, line 51-54). The olefinically unsaturated carboxylic acid monomers include acrylic acids (Col. 5, line 8-19). The olefinically unsaturated sulfonic acid monomers include 2-acrylamido-2-methyl propane sulfonic acid (Col. 5, line 21-29). Generally, from 50 to 99.999 mol% of the hydrogel-forming polymer material will be prepared from such acid group-containing monomers. Two or more monomer types of the described acid group-containing monomers may be copolymerized in order to provide hydrogel-forming polymer material of this requisite acid group-containing monomer content (Col. 5, line 34-45). Some non acid monomers may also be used to prepare the hydrogel-forming polymer compositions including, for example, the water-soluble or water-dispersible esters of the foregoing acid-containing monomers (Col. 5, line 53).

For this purpose of the invention, such hydrogel-forming polymer compositions are considered partially neutralized when at least 25 mol% of the monomers used to form the polymer are acid group-containing monomers which have been neutralized with a salt-forming cation. Suitable salt-forming cations include alkali metal. This percentage of the total monomers utilized which are neutralized acid group-containing monomers is referred to herein as the "degree of neutralization" (Col. 7, line 28-38).

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(3). As to the hydrophilic polymer comprising 1 to 50 mol% of at least one strong acid having pKa less than 3, 50 to 99 mol% of at least one weak acid monomer having pKa greater than 3 in the hydrophilic polymer in the **independent claim 15**, Brandt et al disclose the total amount of acid containing monomers is 50 to 99.999 mol% (See paragraph (2)). The distribution of acid containing monomers for the olefinically unsaturated sulfonic acid monomer and olefinically unsaturated carboxylic acid monomers within the range of 50 to 99.999 mol% can be 1 to 50 mol% for olefinically unsaturated sulfonic acid monomer, 50 to 99 mol% for olefinically unsaturated carboxylic acid as claimed by the applicant. Brandt et al disclose olefinically unsaturated sulfonic acid monomer such as 2-acrylamido-2-methyl propane sulfonic acid which is known a strong acid monomer having pKa less than 3, and a olefinically unsaturated carboxylic acid monomer such as acrylic acid which is known as weak acid having pKa greater than 3.

As to the strong acid monomer being essential its salt form and weak acid monomer being at least 50 mol% in its acid form, at least 5 mol% in its salt form in hydrophilic polymer in the **independent claim 15**, Brandt et al disclose at least 25 mol% of acid containing monomers in salt form (See paragraph (2)) which includes the condition when all olefinically unsaturated sulfonic acid containing monomers to be in salt form, at least half of olefinically unsaturated carboxylic acid monomer in acid form and at least 5 mol% in its salt form as claimed by applicant.

As to the cross-linked hydrophilic polymer component of from 10 to 60 wt% in a hydrogel adhesive in the **independent claim 15**, Brandt et al disclose the crosslinking agent to

be 0.001 mole to 5 mol% (Col. 3, line 64-65) to form crosslinked polymer and the hydrogel-forming polymer material to be 2 to 50 wt% (Col. 4, line 31-33). Based on the substantially identical hydrogel polymer composition disclosed by Brandt et al and by applicant, it is the examiner's position to believe that the hydrogel polymer of Brandt et al would inherently possess the hydrophilicity. Since USPTO does not have proper means to conduct the experiments, the burden now is shifted to the applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980).

As to component (b) from 5 to 80 wt% of water soluble non-ionic humectant and component (c) from 10 to 85 wt% of water in the hydrogel adhesive in the **independent claim 15**, Brandt et al **do not teach** the component (b) and content of component (c).

However, Coles et al **teach** the hydrogel adhesive composition comprising total monomer content to be 15 to 60 wt% (Col. 10, line 23-25, Col. 17, line 55-57), from 3 to 40 wt% of water (Col. 14, line 33-34) and from 10 to 50 wt% of plasticizer (other than water) (Col. 11, line 55-57). The aqueous plasticizing medium optionally additionally comprises a polymeric or non-polymeric polyhydric alcohol (such as glycerol) (Col. 11, line 44-51). Whilst the presence of glycerol or other polyhydric alcohols in other reported formulations has been quoted to provide humectant properties to the hydrogel (Col. 7, line 67- Col. 8, line 3).

The advantage of using the humectant of from 10 to 50 wt% is to prevent the water loss (Col. 8, line 3-7). With the adhesive composition of Coles et al, it improves adhesion so as to facilitate easy application and removal of the article from the wearer whilst ensuring maintenance of the article in the desired position (Col. 1, line 8-15).

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Therefore, it would have been obvious at time the invention was made to prepare the hydrogel adhesive composition by using the hydrogel polymer of Brandt et al and components of humectant, water content of Coles et al in order to obtain the aforementioned advantages.

As to hydrogel adhesive for attachment to mammalian skin in the **independent claim 15**, the hydrogel adhesive composition disclosed by combined teaching of Brandt et al and Coles et al meets the requirements of applicant's claim 1 in terms of types of material added and their contents, it is reasonable to presume that the hydrogel adhesive composition disclosed by combined teaching of Brandt et al and Coles et al would fulfill the utility as presently claimed in light of its chemical similarities. The burden is shifted to applicants to establish that the product of the present claims is not the same as or obvious as that set forth by the references.

As to the adhesive having a pH ranging from 3 to 6 in **dependent claim 16**, and ranging from 3 to 5.5 in **dependent claim 20**, in view of substantially identical hydrogel adhesive composition disclosed by combined teaching of Brandt et al and Coles et al, and by applicant, it is the examiner's position to believe that the hydrogel adhesive composition disclosed by combined teaching of Brandt et al and Coles et al would inherently possess the pH values as claimed. Since USPTO does not have proper means to conduct the experiments, the burden now is shifted to the applicant to prove otherwise. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

As to the limitation of **dependent claim 17**, in view of broad disclosure of Brandt et al, it includes the acid containing monomers distribution of 5 to 45 mol% of strong acid such as 2-acrylamido-2-methylpropanesulfonic acid having pKa less than 3 and from 60 to 95 mol% of weak acid such as acrylic acid having pKa greater than 3 (Col. 5, line 34-45).

As to the limitation of **dependent claim 18**, in view of broad disclosure of Brandt et al, it includes the weak acid monomer distribution of from 60 to 90 mol% in its acid form and 10 to 40 mol% in its salt form (Col. 7, line 28-38).

As to the limitation of **dependent claim 21**, the aqueous plasticizing medium optionally additionally comprises a polymeric or non-polymeric polyhydric alcohol (such as glycerol) (Col. 11, line 44-51). Whilst the presence of glycerol or other polyhydric alcohols in other reported formulations has been quoted to provide humectant properties to the hydrogel (Col. 7, line 67-Col. 8, line 3).

As to the limitation of **dependent claims 22 and 30**, Coles et al disclose: The adhesive may also in addition find application to attach articles to the skin such as ostomy devices, Col. 18, line 67; Because the hydrogel adhesive disclosed by combined teaching of Brandt et al and Coles et al is substantially identical to the hydrogel adhesive in the applicant's claim 15, it will be useful in a disposable human waste management by being disposed on a wearer facing surface as well, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

As to the limitation of **dependent claims 23 and 31**, Coles et al disclose as cited: The disposable absorbent article is described below by reference to a sanitary napkin, Col. 16, line 45-46; The sanitary napkin has two main surfaces, a body contacting or wearer facing surface on which the adhesive is applied and a garment facing or contacting surface, Col. 16, line 64-66.

(4). As to the limitations of the **independent claim 24**, the disclosure of Brandt et al and Coles et al is incorporated herein by reference, the most subject matters of cross-linked hydrophilic polymer, glycerol humectant, water and their contents, the 2-acrylamido-2-methylpropanesulfonic acid monomer of from 8 to 30 mol% and acrylic acid monomers of from 70 to 92 mol% and 20 to 40 mol% in salt form in acrylic acid monomers, the adhesive having pH ranging from 3.5 to 5 has been recited in the applicant's claims 15, 16 and 19, and has been discussed in the paragraph (3).

As to the water activity ranging from 0.35 to 0.95 in the **dependent claim 25**, Coles et al disclose a water activity of from 0.4 to 0.9, in view of substantially identical hydrogel adhesive composition disclosed by combined teaching of Brandt et al and Coles et al, and by applicant, it is the examiner's position to believe that the hydrogel adhesive composition disclosed by combined teaching of Brandt et al and Coles et al would inherently possess the water activity as claimed. Since USPTO does not have proper means to conduct the experiments, the burden now is shifted to the applicant to prove otherwise. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

As to the measurements at 25 °C for elastic modulus, viscous modules of hydrogel adhesive and ratio G''₂₅ (1 rad/s)/G'₂₅ (1 rad/s) ranging from 0.1 to 1 in the **dependent claim 26**, Coles et al disclose an elastic modulus at 1 rad/s from 700 to 15,000 Pa, an viscous modulus at 1 rad/s of from 400 to 14,000 Pa (Col. 8, line 24,27). Therefore the ratio of G₃₇'= 500 Pa/G₃₇''=1000 Pa is 0.5. Typically the elastic modulus is measured over a range of 0.01-100 rad/s at a given temperature. For skin applications the appropriate temperature is 37 °C, Col. 8, line 34-37. Although the elastic modulus G' and viscous modulus G'' of Coles et al is measured at 37 °C, it

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would include or overlap the range of 400 Pa –20,000 Pa of G', range of 100 to 15,000Pa of G" and ratio ranging from 0.1 to 1 if Hydrogel adhesive of Brandt et al and Cole et al with same composition of instant claim 24 is measure at 25°C. Since USPTO does not have proper means to conduct experiments, the burden of proof is now shifted to the applicant to establish the difference. *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980).

As to the adhesive having contact angle of at least 40 degrees in the **dependent claim 27** and peel force on dry skin ranging from 0.3N/cm to 4N/cm in the **dependent claim 28**, Coles et al disclose the quantitative method to determining average peel force required to remove a skin at a specified peel angle and speed. However, Coles et al do not provide test results of samples. In view of substantially identical hydrogel composition disclosed by combined teaching of Brandt et al and Coles et al, and by applicant, it is examiner position to believe that the hydrogel of Brandt et al and Coles et al would inherently possess the Peel strength on dry skin ranging from 0.3 N/cm to 4N/cm with contact angle at least 40 degree. Since USPTO does not have proper means to conduct experiments, the burden of proof is now shifted to the applicant to establish the difference. *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980).

(5). As to the limitations of **dependent claim 29**, the disclosure of Brandt et al and Coles et al is incorporated herein by reference, the most subject matters of water activity from 0.45 to 0.75, contact angle at least 60 degree, peel force on dry skin from 1N/cm to 3 N/cm and elastic modulus, viscous modulus, their ratio measured at 25 degree C in applicant's claim 29 has been recited in applicant's claims 25-28 by either broader or narrower scope and the rejection has been discussed in paragraph (4) and the same rationale is applicable for instant claim 29.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ives Wu whose telephone number is 571-272-4245. The examiner can normally be reached on 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Examiner: Ives Wu
Art Unit: 1713
Date: November 22, 2005


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SUPERVISORY PATENT EXAMINER
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